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10/803,550	03/17/2004	Patrick Fogarty	TOSK-007CIPCON	5663

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EXAMINER	
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1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,550	FOGARTY, PATRICK	
	Examiner	Art Unit	
	Magdalene K. Sgagias	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-15,27 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 13-15, 27 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/27/07;7/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 7/17/07 have been fully considered but they are not persuasive. The amendment has been entered. Claims 11, 13-15, 27 and 31 are pending and under consideration. Claims 1-10, 12, 16-26, 28-30 and 32-38 have been canceled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11, 13-15, 27 and 31 rejection under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is **withdrawn**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 13-15, 27, and 31 rejection under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (U.S. Patent 6,475,798 B2) is **withdrawn**.

Applicant's arguments are moot in view of new rejections below.

Claims 11, 13-15, 27, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (U.S. Patent 6,291,243 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Fogarty et al. teach and claim a method of inserting an exogenous nucleic acid into a non- insect target cell genome using a P element derived vector (claim 12). The P element derived vector comprises a pair of P element transposase recognition sites flanking at least two non- insect cell transcriptionally active expression modules each comprising a coding sequence and a promoter (claim 1). The P element vector taught by Fogarty et al. further comprises that said transposase recognition sites are 31 base pair inverted repeats (claim 6). Fogarty et al. teaches that the P element vector comprises an inter P feet domain that is at least 50 bp in length, or usually at least 1000 bp in length corresponding to the nucleic acid to be inserted into the host genome (col. 4 lines 1-11). This teaching by Fogarty anticipates that a single transcriptionally active gene is separated from a P element transposase domain by a distance of about 1000 bp or less. The claims in the 243' patent are drawn to a method of using a P element vector that comprises at least two non-insect cell genes flanked by a pair of P element transposase recognition sites, however Fogarty et al. in their specification teach that a single gene can be flanked by said transposase recognition sites (col. 5 lines 5-9). Fogarty et al. explicitly states that " Vectors of this embodiment that include a single transcriptionally active

gene may be prepared and used as described below, where the following description is provided in terms of vectors that include at least two transcriptionally active genes." (col. 5 lines 5-9). Fogarty et al. further teach that the P element vector can be used to insert exogenous or endogenous nucleic acids into the genomes of mammalian cells including rat and murine (col. 5 lines 42-59). Fogarty et al. further teach that a second vector can be delivered using the claimed method (claim 14). With regard to the claimed mouse made by the claimed method, the prior art is enabling to the extent that a transgenic mouse is created using the claimed method and the method disclosed in the 243' patent. Fogarty teaches that the claimed method, which is a transformation method, can be used for the creation of transgenic animals, including rodents (col. 1 lines 16-28). Thus Fogarty et al. clearly anticipate the claimed method.

Applicant's arguments are moot in view of new rejections.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.\

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-15, 17-18, 27-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Khillan et al. (Developmental Biology, 1985, Vol. 109, pgs. 247-250) is **withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13-15, 27 and 31 rejection under 35 U.S.C. 112, first paragraph, is **withdrawn** in view of new rejections below.

Claims 11, 13-15, 27 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp proximity to one of the P-element transposase recognized sequences and a transposase domain, and a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said mouse, does not reasonably provide enablement for a method of inserting an exogenous nucleic acid into the genome of a mouse or rat by way of the claimed methods. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims are drawn to a method of inserting an exogenous nucleic acid into the genome of a mouse or rat, said method comprising: introducing into said mouse or rat a P-element derived vector comprising said exogenous nucleic acid under conditions sufficient for transposition to occur, wherein said vector comprises a pair of P-element transposase recognized insertion sequences flanking a heterologous promoter and a single transcriptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated from one of said P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less, so that said exogenous nucleic acid is inserted into said genome.

The working examples provided by the specification teach that male mice were co-injected with a C3.1 and transposase vector via system tail vein injection (pg. 18 lines 6-14). The specification continues to teach that, "Depending on the structure of the vector itself, i.e., whether or not the vector includes a region encoding a product having P element transposase activity, the method may further include introducing a second vector into the animal which encodes the requisite transposase activity" (pg. 11 lines 11-15). The specification continues to teach that co-injection of said vectors resulted in successful integration of the C3.1 vector in a dose-dependent manner into the genomes of said mice that was determined by PCR analysis in testis, liver, spleen, heart, lung, brain, and intestine tissue (pg. 18 lines 16-23 bridge pg. 19 lines 5-17). The specification continues to teach that said vectors were heritable when transgenic mice were bred, resulting in up to 71% of offspring being transgenic (pg. 19 lines 23-24 bridge pg. 20 lines 1-6). However, the specification has failed to disclose a method of inserting an exogenous nucleic acid into the genome of a rat other than mouse.

Whereas the nature of the invention is a method of creating transgenic mouse or rat animal, the art teaches that the field of transgenesis is unpredictable. The art teaches that transgenic mouse lines are generated by microinjection of the linear DNA of interest into the nucleus of an oocyte or transfected into embryonic stem (ES) cells, which then randomly integrates into the genome (Ristevski, Molecular Biotechnology, Vol. 29, 2005, pg. 159 col. 1 parag. 2 lines 1-5). Currently only mouse ES cells have been established that result in a transgenic animal (Smith, 2002, J. of Biotechnology, Vol. 99, pg. 3 col. 1, parag. 4 lines 1-3). With regard to transgene integration the art teaches that the site of integration is uncontrolled and yet is critical due to the possibility of integration into a silent locus. Random integration may occur, resulting in the insertional inactivation (insertional mutagenesis) of a gene at the site of integration, resulting in a loss of function that may be mistakenly attributed to over expression of the transgene (Ristevski, pg. 159 col. 1 parag. 2 lines 5-14). Further, insertional mutagenesis of a gene may not be immediately apparent if a recessive gene has been inactivated, as phenotypic abnormalities will not be evident until homozygous transgenic lines have been established (Ristevski, pg. 159 col. 1 parag. 2 lines 14-19). The site of integration may also result in altered tissue specificity, although the promoter used behaves differently at its normal chromosomal localization, with neighboring regulatory elements potentially influencing the transcriptional activity of the transgene (Ristevski, pg. 159 col. 1 parag. 3 lines 1-7). This is known as chromosomal position effects, where host sequences surrounding the site of transgene integration can alter the expected expression pattern, turning it ectopic or not detectable (Montoliu, 2002, Cloning and Stem Cells, Vol. 4, pg 39, col. 1). With regard to copy number the art teaches that controlling the transgene copy number (usually integration is a singular event with multiple copies integrated in tandem) is also problematic in the generation of transgenic animals (Ristevski, pg. 159 col. 1 parag. 3 lines 7-11). A high tandem copy number

results in a gene silencing effect, and further, is undesirable if the effect of a gene dosage is being addressed, as multiple copies will not recapitulate relevant levels of expression (Ristevski, pg. 159 col. 1 parag. 3 lines 11-14 bridge col. 2 parag. 1). With regard to transgene expression, the art teaches bluntly that, "many transgenes work poorly" (Houdebine, 2002, J. of Biotechnology, Vol. 98, pg. 150, col. 1 parag. 4 line 1). Transgene expression is often very low or not specific of the promoter added in the gene construct, and are generally attributed to position effects in chromatin as discussed above (Houdebine, pg. 150, col. 1 parag. 4 lines 1-5). The art continues to teach that a transgene is generally poorly expressed when it contains a cDNA rather than the corresponding genomic DNA sequence with its introns, has multiple copies integrated in the same site, and when a bacterial gene is used (Houdebine, pg. 150 col. 2 lines 4-9). Overexpression of a transgene of interest also has inherent problems. This is often the case when the overproduced protein shares only a part of the properties of an endogenous protein, which can result in inhibition of the endogenous protein, by the transgene of interest working in a transdominant negative manner (Houdebine, pg. 152, col. 2 parag. 4). The art continues that the generation of transgenic animals routinely involves one of two methods of exogenous DNA delivery to the recipient cells, retroviral infection or microinjection (Smith, pgs. 5-11). However, each method possesses significant unpredictability for the skilled artisan to implement. Retroviral vectors result in inconsistency and irreproducibility of transgene expression due to random integration with host DNA (Smith, pg. 6, col. 1 parag. 2), and instability due to the integrated retroviral DNA possessing the ability to spontaneously reactivate (Smith, pg. 6, col. 1 parag. 5). Microinjection of recipient cells with exogenous DNA presents the problem of mosaicism to the skilled artisan. The majority ($\approx$ 85%) of pronuclear microinjection-derived transgenic founders are mosaics of transgenic and non-transgenic cells (Smith, pg. 7, col. 2 parag. 2 lines 1-4). This becomes problematic since transmission of the

transgene is dependent upon the existence and extent of germline colonization by transgene-containing cells, so that when transmission does occur, the transgene is inherited in a Mendelian fashion resulting in only a small portion of the transgene being passed onto offspring (Smith, pg. 7, col. 2 parag. 3, bridge pg. 8 col. 1 lines 1-8). In view of the art summarized above, the skilled artisan at the time of filing would surmise that the field of transgenesis is very unpredictable, and thus would require and undo amount of experimentation without a predictable degree of success to make and use the claimed transgenic rat animal.

It also important to note that the age and/or weight of the mice have not been disclosed by the specification. Since the injections of the vectors were done systemically via tail vein, it is assumed that the mice were at least born, at a minimum, and still not at the embryonic developmental stage. As stated above, the art teaches that transgenesis in animals other than mice is highly unpredictable. This applies also to the P-element vector system, even though the transgenic mice created by the claimed method were already delivered (i.e. not in the womb). The difficulty and unpredictability in producing rat transgenic species involves significant inventive steps that each adds a level of unpredictability and would place an undue burden of experimentation by a skilled artisan to determine the specific heterologous promoter, and a single transcrtiptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated by one of said P-element trnasposase recognized insertion sequences by a distance of about 1,000 bp or less so that exogenous nucleic acid is inserted into said genome to produce rat transgenic animal other than mouse.

Therefore, in view of the lack of guidance provided by the specification as well as the unpredictability of the art, the claimed invention is not enabled for its full breadth and limiting the scope of the claimed invention to a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element

derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences and a transposase domain, and a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said mouse is proper.

Applicants argue that have amended the claims to specify the claimed method is performed in a mouse. Applicants argue, however, applicants have also included the rat embodiment, based on the disclosure in the specification at page 19, lines 18-22, wherein it is set forth that male mice and rats were injected into their testis and animals gave transgenic offspring.

These arguments are not persuasive because the mere disclosure that, rats were also injected into their testis does not provide sufficient guidance to correlate the creation of a transgenic mouse to the creation of a transgenic rat by way of the claimed method because as discussed above the difficulty and unpredictability in producing rat transgenic species involves significant inventive steps that each adds a level of unpredictability and would place an undue burden of experimentation by a skilled artisan to determine the specific heterologous promoter, and a single transcrtiptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated by one of said P-element trnasposase recognized insertion sequences by a distance of about 1,000 bp or less so that exogenous nucleic acid is inserted into said genome to produce rat transgenic animal other than mouse.

Therefore, applicant's argument that once transgenesis is demonstrated in one rodent species (mouse) using P-element derived vectors from such a divergent and unrelated species (Drosophilafly of phylum Arthropoda), it is reasonable to conclude that the methods can be extrapolated to other rodent species is similar in manner without undue experimentation is not persuasive commensurate with full scope of the claim. It is noted that the unpredictability of a particular art area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991)*. It is also well established in case law that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. *In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994)*, citing *In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991)*. The guidance provided by the specification to overcome the art recognized unpredictability of a method of producing a genetically modified rat comprising introducing into said mouse or rat a P-element derived vector comprising said exogenous nucleic acid under conditions sufficient for transposition to occur, wherein said vector comprises a pair of P-element transposase recognized insertion sequences flanking a heterologous promoter and a single transcriptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated from one of said P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less, so that said exogenous nucleic acid is inserted into said genome resulting in the expression of a transgene in one or more somatic cells of the transgenic rat.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 13-15, 27 and 31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 11, 13-15, 18, 27, 30-31, 34 of copending Application No. 10/659,802 is **withdrawn.**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 13-15, 28 and 31 rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-17 of U.S. Patent No. 6,475,798 B2 is **withdrawn.**

New-Claim Rejections- Double Patenting

Claims 11, 13-15, 27 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 13-15, 18, 27, 30-31 and 34 of the co-pending application 10/659,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the instant application and the co-pending application is that the instant application claims sequences flanking a heterologous promoter, using the claimed method, wherein the co-

pending application does not specifically claim sequences flanking a heterologous promoter. It is noted that in both cases the specification discloses the use of the same promoters for the creation of the claimed transgenic animals.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter

Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Art Unit 1632

/Anne-Marie Falk/
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